K090562

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SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew Instrument Trays
Date Prepared: February 27, 2009

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Julie Acker RAC
Senior Regulatory Specialist
T: 508-261-3618
F: 508-261-3620
Julie.acker@smith-nephew.com

C. Device Name

Trade Name:	Smith & Nephew Instrument Tray
Common Name:	Sterilization Tray
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes and Other Accessories
Class:	II
Product Code:	KCT
Classification Number:	21 CFR §880.6850

D. Predicate Devices

The subject Smith & Nephew Instrument Trays are substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: Smith & Nephew Instrument Tray 510(k)# K073551

E. Description of Device

The Smith & Nephew instrument trays are designed to contain and protect reusable surgical instruments during transport, sterilization, and storage and to allow optimal exposure of the tray's contents to sterilant during the sterilization process.

F. Intended Use

Smith & Nephew instrument trays are intended to contain Smith & Nephew reusable surgical instruments for convenient organized storage, sterilization and transport between usages. The subject instrument trays are suitable for use in prevacuum steam and high temperature gravity steam sterilization methods. The subject instrument trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated sterilization wrap in order to maintain sterility of the enclosed devices.

Validated Sterilization Parameters:

Method	Temperature	Exposure Time	Drying Time
Pre-vacuum steam	132 – 135 C (270 F – 275F)	4 minutes	30 minutes
High Temperature Gravity Steam	132C (270F)	15 minutes	70 minutes

G. Comparison of Technological Characteristics

The subject Smith & Nephew instrument trays have the same fundamental technological characteristics as the unmodified predicate device. The subject trays are substantially equivalent in design, materials and intended use to the predicate device. There are no significant differences between the proposed and predicate devices that raise new questions of safety or efficacy.

H. Summary Performance Data

Performance testing was conducted in accordance with AAMI ST77:2006 *Containment Devices for reusable medical device sterilization.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2009

Smith & Nephew, Incorporated
Ms. Julie Acker
Senior Regulatory Specialist
Endoscopy, Division
130 Forbes Boulevard
Mansfield, Massachusetts 02048

Re: K090562
Trade/Device Name: Smith & Nephew Instrument Trays
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: February 27, 2009
Received: March 2, 2009

Dear Ms. Acker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud M.D.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K090562

Device Name: Smith & Nephew Instrument Trays

Indications for Use: Smith & Nephew instrument trays are intended to contain Smith & Nephew reusable surgical instruments for convenient organized storage, sterilization and transport between usages. The subject instrument trays are suitable for use in prevacuum steam and high temperature gravity steam sterilization methods. The subject instrument trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated sterilization wrap in order to maintain sterility of the enclosed devices.

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Device models that are the subject of this pre-market notification:

REF	Description
72201939	Tray, BIOSURE™ Easy -Taps
72201940	Tray, BIOSURE™ Notchers
72201938	Tray, BIOSURE™ Taps
72201847	Tray, CROSSTRAC™ Hip Access System
72202202	Tray, ELITE Premium Biceps Tenodesis System

Prescription Use _____ AND/OR Over-The-Counter Use _X_

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Sheila N. Murphy (S)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090562